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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,330

08/08/2006

Minas Theodore Coroneo

37528-503N01US

6478

64046

7590

12/23/2009

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

12/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,330	Applicant(s) CORONEO, MINAS THEODORE	
	Examiner Philip R. Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-21 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/17/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

In the reply filed 8/17/09, applicant amended claims 19 and 21. Claims 19-21 and 31 are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 19, 21 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. (US 3,788,327) in view of Wandel (US 5,807,302). With respect to Claim 19, Donowitz discloses an ocular pressure spike shunt comprising a fluid transfer tube made from a biocompatible, substantially flexible material (Column 3, Lines 19-23). The tube has an inner (distal) end, an outer (proximal) end 34, a tubular lumen disposed therebetween, and a valve 48 for maintaining pressure in the eye at a normal level, said valve opens to permit fluid flow through the tube when a predetermined pressure is exceeded (Column 2, Line 65 through Column 3, Line 2). When implanted in the eye, the shunt is disposed such that the outer end is substantially flush with the outer surface of the cornea, and the inner end opens into the anterior chamber of the eye on the inner surface of the cornea. The implant is fully capable of being inserted into an ocular

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paracentesis incision port and removed from the eye after treatment is complete. See Figures 1, 2, and 4. Regarding claim 21, Donowitz discloses the method of implanting an ocular shunt as described above, comprising forming an incision in the eye, and introducing the shunt (see rejection above) through the incision such that the outer end is flush with the surface of the cornea and the inner surface extends into the anterior chamber of the eye.

Donowitz teaches the ocular implant substantially as claimed, and further teaches a retaining means 46 for holding the inner surface of the implant flush against the inner surface of the eye. Donowitz, however, does not specifically teach that the retaining means comprise increased diameters that abut against the inner and outer surfaces of the cornea.

Wandel teaches an ocular drainage tube for draining aqueous humor from the anterior chamber of the eye. The tube comprises anchoring members at the proximal and distal ends thereof having increased diameters at both ends (30a, 30b). The shunt is sized such that the anchor members snugly engage the inner and outer walls of the cornea. This configuration effectively prevents the glaucoma shunt from moving from its transcorneal position as a result of pressure differences or any other accidental movement (Column 3, Lines 18-44). The use of anchoring means having increased diameters is well known in the art of glaucoma shunts because it provides a mechanically simple means for preventing longitudinal movement of the shunt away from the ocular wall. Therefore, it would have been obvious to one of ordinary skill in the art to modify the glaucoma shunt of Donowitz with the anchor members having,

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enlarged diameters at the proximal and distal ends of Wandel in order to provide a well known, alternate means for preventing movement of the shunt with respect to the ocular wall.

2. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz in view of Wandel, and further in view of Brown et al. (US 5,743,868).

Donowitz and Wandel reasonably suggest an ocular shunt having a pressure-regulating valve substantially as claimed (see rejection above). Donowitz, however, does not specifically teach that the valve operates such that a 10 mmHg pressure differential is maintained. Brown discloses an ocular implant for regulating pressure between the anterior chamber and the exterior of the cornea such that the pressure difference is kept at 10 mmHg, which is considered to be a normal pressure in the anterior chamber (Column 6, Lines 37-44). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the unidirectional pressure control valve of Donowitz and Wandel to regulate fluid flow such that a 10 mmHg pressure differential is maintained in order to keep the anterior chamber of the eye at a natural pressure level.

Response to Arguments

3. Applicant's arguments with respect to the rejection(s) of claim(s) 19-21 have been fully considered and are persuasive. The cited combination of Donowitz and L'Esperance does not teach or suggest a shunt having an enlarged portion at the *distal tip thereof* that abuts against the inner surface of the cornea. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection

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is made in view of newly discovered prior art. Specifically, Wandel generally teaches a shunt having anchors at the distal and proximal tips thereof, said anchors positioned flat against the inner and outer surfaces of the cornea.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
3 December 2009